

Patent US 201C1 Attorney Docket No. 892,280-147

Group Art Unit: Not Yet Assigned

HE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

CAVALERI et al.

Serial No. 10/828,483

Filed: April 16, 2004

For:

METHODS OF ADMINISTERING

DALBAVANCIN FOR TREATMENT

OF SKIN AND SOFT TISSUE INFECTIONS (as amended)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97–1.98, information relating to the above-identified application is hereby disclosed. The accompanying Form PTO-1449 provides a listing of documents that may be relevant to the subject application.

It is requested that the Examiner fully consider the art cited in the accompanying Form 1449, initial the left-most column of the form adjacent each cited reference, and return a copy for Applicants' records. It is further requested that the art be cited on the cover of any patent issuing from the subject application.

CERTIFICATE OF MAILING (37 C.F.R. §1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450.

June 2, 2004

Date of Deposit IR1:1055555.1

Attorney Docket No. 892,280-147

This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b),

that is (1) within three months of the filing date of the application, which is not a continued

prosecution application filed under § 1.53(d); or (2) within three months of entry of the

national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action

on the merits; or (4) before the mailing of a first Office action after filing a request for

continued examination under § 1.114. Thus, no fee is required.

This statement should not be construed as a representation that more material

information does not exist or that an exhaustive search of the relevant art has been made. Nor

does this statement constitute an admission by Applicants or Applicants' agent that the

information provided herein is necessarily prior art to Applicants' invention. Moreover,

Applicants reserve the right to establish the patentability of the claimed invention over any of

the listed documents should they be applied there-against as references.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: June 1, 2004

 $\mathbf{R}\mathbf{v}$

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PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1445 PADEMARY				re required to respond to a collection of information unless it contains a valid OMB control number. Complete if Known		
Substitute for form 14435 700 CM				Application Number	10/828,483	
INF	ORMATION	DIS	CLOSURE	Filing Date	April 16, 2004	
STATEMENT BY APPLICANT				First Named Inventor	CAVALERI et al.	
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(Use as many sheets as necessary)				Examiner Name	Not Yet ASsigned	
Sheet	1	of	1	Attorney Docket Number	892,280-147	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	Dowell, et al. (2003). "Dalbavancin Dosage Adjustments Not Required for Patients with Mild Renal Impairment, " 2003 ECCMID Meeting.	
	2	Stogniew et al. (2003). "Pharmacokinetic Attributes of Dalbavancin: Well Distributed and Completely Eliminated With Dual Routes of Elimination," 2003 ECCMID Meeting.	
	- 3	White et al. (2000). "V-Glycopeptide: Phase1 Single and Mulltiple-dose Placebo Controlled Intravenous Safety, Pharmacokinetic, and Pharmacodynamic Study in Healthy Subjects," Abstracts of the 40th Interscience Conference on Antimicrobial Agents and Chemotherapy, September 2000, page 233.	
12			
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Examiner	Date	
Signature	Consider	ered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: